Pain Medicine
Pain Medicine 2014; 15: 921–928
Wiley Periodicals, Inc.

SPINE SECTION

Original Research Articles

Lumbar Transforaminal Epidural Steroid Injections: Does Immediate Post-Procedure Pain Response Predict Longer Term Effectiveness?

Christine El-Yahchouchi, MD,* John Wald, MD,‡ Jeffrey Brault, DO,§ Jennifer Geske, MS,† Clinton Hagen, MS,† Naveen Murthy, MD,‡ Timothy Kaufmann, MD,‡ Kent Thielen, MD,‡ Jonathan Morris, MD,‡ Felix Diehn, MD,‡ Kimberly Amrami, MD,‡ Rickey Carter, PhD,† Randy Shelerud, MD,§ and Timothy Maus, MD‡

*Department of Anesthesiology, American University of Beirut, Beirut, Lebanon;

Departments of †Health Sciences Research,

‡Radiology and

§Physical Medicine and Rehabilitation, Mayo Clinic, Rochester, Minnesota, USA

Reprint requests to: Christine El-Yahchouchi, MD Department of Anesthesiology, American University of Beirut Medical Center, P.O. Box 11–0236 Riad El-Solh Beirut 1107–2020 Beirut, Lebanon. Tel: 96171465611; Fax: 961-1-745249: E-mail: ce18@aub.edu.lb.

Disclosure: Dr. Maus is on the Board of Directors of the International Spine Intervention Society.

Abstract

Objective. **To assess whether the immediate anesthetic response of pain relief (sensory blockade) or weakness (motor blockade) after lumbar transforaminal epidural steroid injection (TFESI) is associated with longer term effectiveness in pain relief and functional recovery.**

Design. **Retrospective observational study.**

Setting. **Single academic radiology practice.**

Subjects. **Three thousand six hundred forty-five lumbar TFESIs performed on 2,634 subjects.**

Methods. **Subjects completed a pain numerical rating scale (NRS, 0–10) and Roland–Morris disability questionnaire (R-M) prior to and immediately after TFESI (NRS) and at 2 weeks and 2 months follow-up. Successful pain relief was ≥50% NRS reduction; functional success was ≥40% R-M reduction. Post-procedure motor weakness was recorded. Logistic regression models assessed association of immediate post-procedure NRS response, and NRS or R-M response at 2 weeks, with successful outcomes at 2 months. C-index assessed model discrimination; values closer to 1.0 indicated better discrimination.**

Results. **Immediate NRS response was weakly associated with 2-month outcomes (C-index = 0.58). NRS and R-M responses at 2 weeks were more strongly associated with the 2-month response (C-indices 0.77, 0.80, respectively). Post-procedure motor blockade had little association with successful 2-month NRS or R-M outcomes (C-indices 0.51, 0.50, respectively). Patients that responded at 2 weeks were more likely to be responders at 2 months than those who were non-responders at 2 weeks (odds ratio = 6.49, confidence interval 5.38, 7.84).**

Conclusion. **Immediate post-TFESI pain relief does not strongly predict longer term effectiveness in pain relief or functional recovery. Response in pain relief or functional recovery at 2 weeks is more strongly associated with 2-month outcomes.**

Key Words. **Lumbar Transforaminal Epidural Steroid Injection; Immediate Response; Longer Term Effectiveness**

Introduction

Lumbar transforaminal epidural steroid injections (TFESIs) have demonstrated efficacy in explanatory and pragmatic trials [1,2], and clinical effectiveness in larger observational studies [3] for the relief of pain and improvement in physical functioning in patients with radicular pain. TFESIs typically involve the administration of local anesthetic and corticosteroid into the ventral epidural space adjacent to the target nerve thought to be causal of the patient's pain. Patients frequently exhibit significant relief of the index pain immediately following the procedure from the administered anesthetic and may have a temporary impairment of motor function. This suggests that the correct neural structure has undergone appropriate blockade, but it is not known if this is associated with longer term successful pain relief and functional improvement.

The purpose of this study was to determine if there was an association between immediate relief of index pain (sensory blockade) and/or motor weakness (motor blockade) and longer term improvement in pain and physical function. This was previously addressed in computed tomography (CT)-guided cervical transforaminal injections [4], but no such study for lumbar TFESIs has been reported.

Methods

The study was approved by the local Institutional Review Board and complied with all Health Insurance Portability and Accountability Act requirements.

Patient Population

The study cohort included 3,645 TFESIs performed in 2,634 patients between January 2006 and February 2011 at the L4–5, L5-S1 or S1 foraminal levels. Patient demographics are summarized in Table 1. Patients received lumbar TFESIs as therapy for radicular pain, with or without findings of radiculopathy, which had proven unresponsive to conservative care or had failed more aggressive interventions at other institutions. Nearly all study patients were referred for TFESI following evaluation in the Mayo Multidisciplinary Spine Center (a cooperative venture of Physical Medicine and Rehabilitation, and Neurology physicians), Orthopedic Spine Surgery, or Neurosurgery. TFESI were planned and targeted based on a synthesis of clinical data including the radicular distribution of the pain pattern, physical findings (deep tendon reflex alteration, sensory loss, weakness), electromyography if available, and advanced imaging (magnetic resonance imaging, CT, or CT/myelography). All patients had advanced imaging prior to the procedure and the TFESI was planned to best deliver the pharmaceutical to the target nerve. Neural compressive lesions included disc herniations, synovial cysts, and fixed bony lateral recess or foraminal stenosis. The study cohort included patients receiving more than one injection when there were at least 2 months between injections. The cohort was consecutive within the bounds of the inclusion criteria noted earlier. There were 2,174 procedures with data available for analysis.

Immediately prior to the procedure, patients completed two outcome measures: the Roland–Morris disability questionnaire (R-M, 23-point Deyo modification [5] which addresses functional disability due to radicular pain) and a pain numerical rating scale score (NRS, 0–10, where 0 was no pain and 10 the worst pain imaginable). Successful categorical outcomes were defined as reduction in pain by at least 50% or 0/10 pain at the time of measurement. Successful functional outcome was a reduction in R-M score by 40% or more, which is the minimal clinically important difference [6].

Table 1 Study population demographics and procedural characteristics

Characteristic	% or mean ± SD
Gender-male	45.3
Age	62.2 ± 16.0
Duration of pain	
0–3 months	22.4
4–6 months	13.9
7–12 months	8.9
>1 year	54.8
Level of injection	
L4–5	23.7
L5-S1	44.6
S1	31.7
NRS scores	
Pre-pain	5.8 ± 2.2
Post-pain	1.6 ± 2.1
Week 2 pain	3.7 ± 2.7
Month 2 pain	3.5 ± 2.7
R-M scores	
Pre-R-M	12.5 ± 5.2
Week 2 R-M	9.2 ± 5.1
Month 2 R-M	8.6 ± 5.2

NRS = numerical rating scale; R-M = Roland–Morris disability questionnaire; SD = standard deviation.

Procedural Technique

TFESIs were performed in accord with the guidelines of the International Spine Intervention Society [7]. The procedural technique utilized on this study cohort has been previously reported [8]. Following exclusion of vascular or intrathecal uptake and demonstration of a satisfactory epidural spread pattern, a 20 mg lidocaine (1 mL of 2% lidocaine) test dose was injected. If there was no neurological change over the next 1–2 minutes, corticosteroid was injected (betamethasone sodium phosphate/ betamethasone acetate [Celestone] 12 mg in 2 mL, American Regent, Inc., Shirley, NY, USA; triamcinolone acetonide [Kenalog], 80 mg in 2 mL, Bristol-Myers Squibb, New York, NY, USA; or preservative-free dexamethasone sodium phosphate, 10 mg in 1 mL, APP Pharmaceuticals, LLC, Lake Zurich, IL, USA). The patient was taken to a recovery area and re-evaluated by the treating physician in 10–15 minutes. A post-procedure pain score (NRS, 0–10) was recorded, typically with the patient ambulating or performing maneuvers or adopting postures that would typically provoke the index pain. The presence of lower extremity weakness as a manifestation of motor blockade was also noted at this time.

Clinical Follow-Up Data

All subject data were entered into a SAS database. An independent paramedical assessor obtained follow-up R-M and NRS data via telephone interview at 2 weeks and 2 months post-procedure. At least three attempts were made to contact each subject at each time point.

Statistical Analysis

Analyses were conducted to test for association of patients' immediate post-procedure and 2-week NRS and R-M scores with their follow-up (2 month) NRS and R-M scores using a combination of Spearman rank correlations and logistic regression models. The logistic regression models were used to determine if the immediate post-procedure NRS score, percent change from baseline to immediate post-procedure NRS score, or complete relief status were predictors of a ≥50% improvement in the NRS or ≥40% improvement in the R-M score at 2 weeks or 2 months. This method was also used to determine if the 2-week R-M or NRS scores predicted response in R-M or NRS scores at 2 months. The outcomes, percentage of change in NRS and R-M scores, were calculated from pre-procedure to 2 weeks and from pre-procedure to 2 months. Baseline pain was included as a predictor in all models to control for confounding due to differences in initial severity of pain. The presence of a motor block immediate post-procedure was also assessed for association with 2-month outcomes. C-indices assess model fit. The range of C-index values is 0–1.0; values closer to 1.0 indicate better fit. C-index values less than 0.7 have no to poor discriminatory power, values of 0.7–0.8 have acceptable discrimination, values of 0.8–0.9 indicate excellent discrimination, and 0.9–1.0 indicates outstanding discrimination [9].

To further assess the association of immediate and 2-week responses with 2-month outcomes, contingency tables were constructed with binary classifications of the occurrence of a response (50% reduction in NRS; 40% reduction in the R-M score) immediately following the procedure and at 2 weeks. The association of the 2-month outcome with the presence or absence of motor blockade was also assessed. These analyses did not adjust for pre-procedure pain. The odds ratio (OR) along with the 95% confidence intervals was used to measure the size effect of the association.

Missing data due to loss to follow-up was unavoidable in the study. To assess the possible impact of the missing data on the study's conclusions, sensitivity analyses were conducted using data imputation techniques [10]. Initially, NRS data lost to follow-up were imputed as all non-responders or all responders. These single imputation analyses were complemented with a multiple imputation analysis. This analysis used regression models to impute the missing data 10 times based on the sample data distributions as well as the baseline and prior available data for each subject. The estimated effect from each of the 10 multiple imputation data sets was combined into a common OR.

Statistical analyses were conducted by using SAS, Version 9.3 (SAS Institute, Cary, NC, USA). *P* values less than 0.05 were considered statistically significant.

Results

The mean (standard deviation) NRS and R-M scores prior to the 2174 procedures in the cohort were 5.8 (2.2) and 12.5 (5.2), respectively. Local anesthetic blockade, an NRS pain score of 2 or less immediately following the TFESI, was achieved in 73.3% of procedures (Figure 1). The categorical pain relief and functional recovery outcomes at 2 weeks and 2 months, including stratification by steroid type, have been previously reported [8].

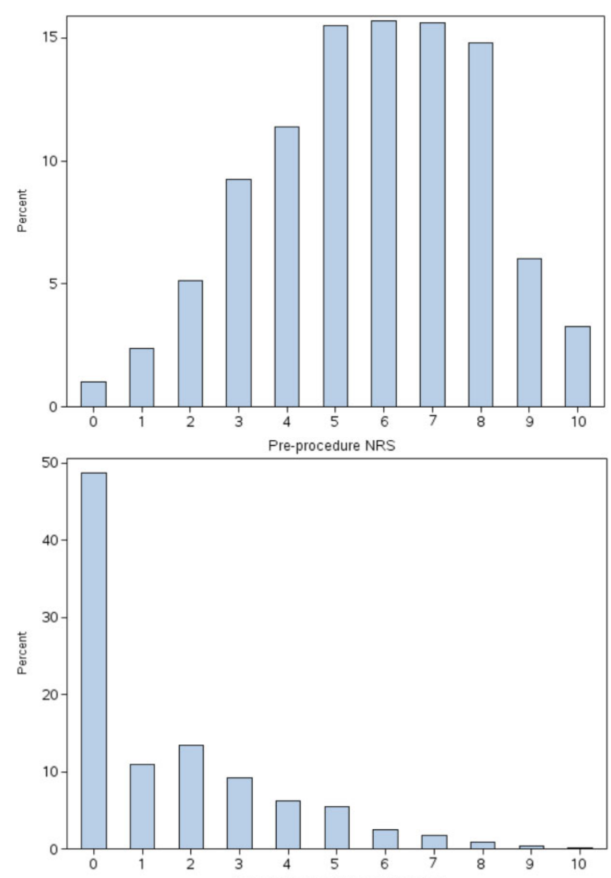

Figure 1 Distribution of numerical rating scale (NRS) scores immediately prior to transforaminal epidural steroid injection (TFESI) and immediately post-TFESI. Anesthetic blocks were achieved in most patients.

Table 2 Spearman rank correlations of NRS immediately and 2 weeks post-injection with NRS and R-M 2 weeks and 2 months post-injection (all P values <0.0001)

Post-procedure score	NRS 2 week	NRS 2 month	R-M 2 week	R-M 2 month
NRS Immediate	0.24	0.20	0.21	0.21
NRS 2 weeks	—	0.59	0.66	0.51

NRS = numerical rating scale of pain; R-M = Roland–Morris disability questionnaire.

The immediate pain response following TFESI was only weakly associated with successful response in pain or functional improvement at 2 months follow-up (Spearman correlations, ρ = 0.20, 0.21, respectively, Table 2). The pain score at 2 weeks was much more strongly associated with 2 month response in both pain (ρ = 0.59) and function (ρ = 0.51).

The logistic regression models similarly demonstrate that the immediate pain response following TFESI, either as numerical pain ratings (Table 3, C-index = 0.58) or as percentage change from baseline (Table 4, C-index = 0.58) was a poor predictor of patients achieving responder status of ≥50% pain relief at 2 months. It was also a poor predictor of ≥40% improvement in R-M score at 2 months (C-index = 0.59 and 0.58 for absolute pain score and percentage improvement, respectively). The pain score at 2 weeks provided acceptable discrimination with the 2-month response (C-index = 0.77); R-M score at 2 weeks demonstrated acceptable to excellent discrimination with the 2-month R-M score (C-index = 0.80).

The logistic regression model predictions of probabilities of patients achieving responder status for pain relief based

Table 3 Logistic regression models using pain and R-M scores as predictors of poor response (all P values <0.0001)

Improvement (adjusted for baseline)	Predictor	OR	95% CI	C-index
≥50% NRS at 2 weeks	NRS immediate	1.152	(1.109, 1.196)	0.569
≥50% NRS at 2 months	NRS immediate	1.138	(1.087, 1.191)	0.577
≥50% NRS at 2 months	NRS 2 week	1.580	(1.506, 1.657)	**0.770**
≥40% R-M at 2 weeks	NRS immediate	1.135	(1.092, 1.180)	0.576
≥40% R-M at 2 months	NRS immediate	1.137	(1.086, 1.191)	0.588
≥40% R-M at 2 months	R-M 2 week	1.353	(1.314, 1.393)	**0.802**

Odds ratios estimated are for a one-unit change in predictor variable and have been adjusted for baseline (pre-procedure) pain as measured by the NRS.
OR = odds ratio; CI = confidence interval; R-M = Roland–Morris disability questionnaire; NRS = numerical rating scale of pain.Bold format highlights the significant finding.

Table 4 Logistic regression models using % change in NRS and R-M scores as predictors of poor response (all P values <0.0001)

Improvement (adjusted for baseline)	Predictor	OR	95% CI	20% OR	C-index
≥50% NRS at 2 weeks	% Immediate change	1.008	(1.006, 1.010)	1.160	0.579
≥50% NRS at 2 months	% Immediate change	1.007	(1.005, 1.010)	1.140	0.578
≥50% NRS at 2 months	% Change 2 weeks	1.025	(1.022, 1.027)	1.500	**0.776**
≥40% R-M at 2 weeks	% Immediate change	1.006	(1.004, 1.008)	1.120	0.570
≥40% R-M at 2 months	% Immediate change	1.005	(1.003, 1.008)	1.100	0.579
≥40% R-M at 2 months	% Change 2 weeks	1.017	(1.015, 1.020)	1.340	**0.726**

Odds ratios estimated are for a one-percentage point change in predictor variable and have been adjusted for baseline (pre-procedure) pain as measured by the NRS.
OR = odds ratio; CI = confidence interval; R-M = Roland–Morris disability questionnaire; NRS = numerical rating scale of pain.

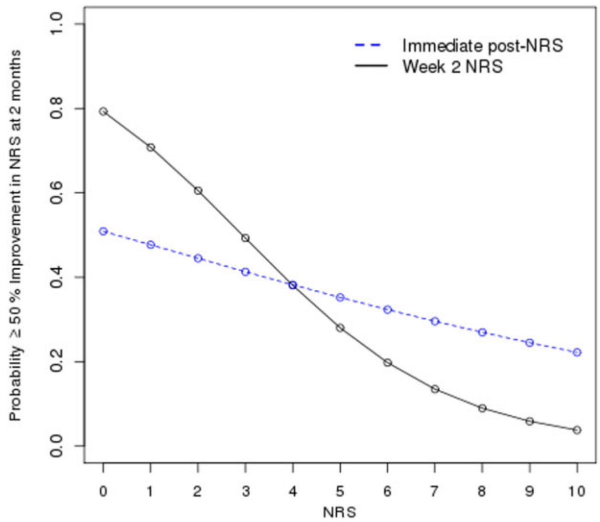

Figure 2 Model-based probabilities of ≥50% improvement in numerical rating scale (NRS) at 2 months by immediate or 2-week pain outcomes (adjusted for a baseline NRS score of 6).

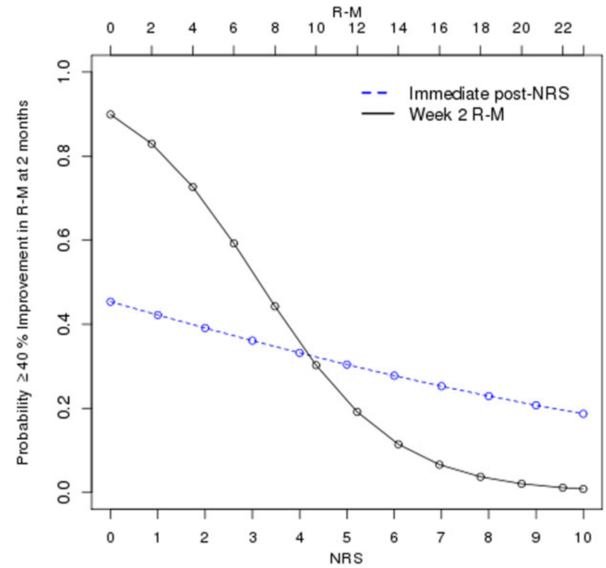

Figure 3 Model based probabilities of ≥40% improvement in Roland–Morris disability questionnaire (R-M) at 2 months by immediate numerical rating scale (NRS) or 2-week R-M outcomes (adjusted for a baseline R-M score of 13).

on immediate and 2-week pain scores are presented graphically in Figure 2. The greater discrimination of the outcome by 2-week scores (solid line) is evident. Figure 3 depicts similar probabilities for achieving ≥40% improvement in R-M scores based on immediate pain scores and 2-week R-M scores.

Contingency tables of the association between 2-month response in pain relief, and the immediate and 2-week responses (Table 5) demonstrate ORs of 1.67 (1.34, 2.07) for the immediate pain response and 6.49 (5.38, 7.84) for the 2-week response. Similarly, examining the association with 2-month R-M scores, Table 6 yields OR = 1.46 (1.17, 1.82) for the immediate NRS response vs OR = 7.32 (6.03, 8.88) for the 2-week R-M score.

The presence of transient weakness (motor blockade) immediately following TFESI did not predict either pain response or functional improvement at 2 months follow-up in the logistic regression analysis. The C-index values showed no discrimination for 2-month pain relief (C = 0.511) or functional improvement (C = 0.5003). Contingency tables likewise reveal (Table 7) essentially no association between the presence of a motor blockade with 2-month NRS response (OR = 1.16 [0.94, 1.44]) or R-M response (OR = 1.00 [0.81, 1.25]).

The magnitude of association between the 2-week NRS score and the 2-month outcome as estimated by the

Table 5 Contingency tables of 2-week and immediate pain response association with 2-month pain response (NRS)

	Response at 2 months			
	>50% improvement NRS, or NRS = 0	<50% improvement NRS	OR	95% CI
Response at 2 weeks			6.49	(5.38, 7.84)
≥50% improvement in NRS, or NRS = 0	712	347		
<50% improvement NRS	267	845		
Immediate response			1.67	(1.34, 2.07)
≥50% improvement in NRS, or NRS = 0	823	906		
<50% improvement NRS	157	288		

N = 2,171 for 2-week responses; three patients of the cohort were missing data.
OR = odds ratio; CI = confidence interval; NRS = numerical rating scale of pain.

Table 6 Contingency tables of 2-week response and immediate response associations with 2-month functional improvement response (R-M)

	Response at 2 months			
	>40% improvement R-M	<40% improvement R-M	OR	95% CI
Response at 2 weeks			7.32	(6.03, 8.88)
≥40% improvement in R-M	572	276		
<40% improvement R-M	292	1,031		
Immediate response			1.46	(1.17, 1.82)
≥50% improvement in NRS, or NRS = 0	719	1,010		
<50% improvement NRS	146	299		

N = 2,171 for 2 week responses; 3 patients of the cohort were missing data.
OR = odds ratio; CI = confidence interval; R-M = Roland–Morris disability questionnaire; NRS = numerical rating scale of pain.

logistic regression model (Table 3) may appear discordant with the OR measured in the contingency table (Table 5). However, the logistic regression-based estimate, OR = 1.580, is for a single unit change in the NRS, whereas the contingency table uses a dichotomization for a 50% reduction, with an OR = 6.49. Using a larger change in the 2-week pain score of 3 units, the logistic regression model OR would be estimated at 4.0, which is more comparable with the contingency table estimate. Also, the contingency table is unadjusted for pre-procedural pain, which could result in some confounding of results.

The analysis to assess the impact of missing data is presented in Table 8. From the initial cohort of 3,645 injection procedures, follow-up data were available for 2,174 injections (60%) at 2 months. In both single and multiple imputation analyses, the ORs remained much greater for the 2-week response as a predictor of 2-month outcomes (OR = 4.5–10.4) than the immediate response (OR = 1.29–1.62).

Discussion

This study demonstrates that immediate relief of index pain following TFESI, however encouraging at the time, is not strongly associated with longer term outcomes. While sensory and/or motor blockade may indicate that the appropriate segmental nerve has been exposed to the local anesthetic component of the injectate, the longer term beneficial effect is dependent on the steroid-induced reduction in the local inflammatory response in the ventral epidural space that has rendered the segmental nerve irritable and subject to ectopic discharge [11]. It is not surprising, therefore, that the response in pain relief and functional improvement seen at 2 weeks post-injection, when the anti-inflammatory effect of the delivered corticosteroid is thought to be engaged, is more strongly associated with longer term outcomes. Factors thought to influence this anti-inflammatory effect include the degree of neural compression, the appropriate delivery of the corticosteroid, and central sensitization.

Table 7 Contingency tables of motor blockade associations with 2-month pain (NRS) and functional improvement (R-M) responses

	Response at 2 months			
	≥50% improvement NRS, or NRS = 0	<50% improvement NRS	OR	95% CI
Motor blockade			1.16	(0.94, 1.44)
Yes	199	215		
No	781	979		
	≥40% improvement R-M	<40% improvement R-M		
Motor blockade			1.00	(0.81, 1.25)
Yes	165	249		
No	700	1,060		

OR = odds ratio; CI = confidence interval; R-M = Roland–Morris disability questionnaire; NRS = numerical rating scale of pain.

Table 8 Sensitivity analysis of assumptions of missing data using NRS 50% improvement outcome

	Predictor of 2 month NRS response	
Missing data assumptions	2-week NRS response OR (95% CI)	Immediate NRS response OR (95% CI)
None (use all available data)	6.49 (5.38, 7.84)	1.67 (1.34, 2.07)
Missing assumed poor outcome	10.35 (8.74,12.26)	1.62 (1.33, 1.96)
Missing assumed favorable outcome	4.51 (3.88, 5.23)	1.29 (1.09, 1.53)
Multiple imputation	6.17 (5.08, 7.39)	1.33 (1.10, 1.61)

OR = odds ratio; CI = confidence interval; NRS = numerical rating scale of pain.

Radicular pain is the product of both compression of neural tissue and an inflammatory response; tumor necrosis factor α, phospholipase A_2, interleukins 1 and 6, and nitric oxide have been implicated in the inflammatory response associated with disc herniations [12]. Intraradicular venous hypertension is causal of the inflammatory response at fixed stenotic lesions [13]. Disc herniations and fixed stenotic lesions are likely a continuum of neural compression and inflammatory components. When the inflammatory component dominates, patients may be more responsive to TFESIs than in highly compressive lesions. The studies of Choi et al. [14], and Ghahreman and Bogduk [15] noted a significant association between the degree of neural compression and TFESI outcomes; patients with greater degrees of compression did less well.

The technique, and hence the site, of corticosteroid delivery may also affect outcomes. The ventral ramus may be successfully blocked by an extraforaminal local anesthetic injection, but this is not the ideal distribution of corticosteroid. Spread of injected contrast medium, and by extension corticosteroid, to the ventral epidural space is associated with significantly better pain reduction outcomes [16]. Another study demonstrated a trend toward better pain relief outcomes when contrast reached preganglionic neural tissue [17].

Alternations in neural signaling central to the neural foramen may also create discordance between a successful anesthetic blockade at the foramen and longer term therapeutic anti-inflammatory effect. Spinal cord physiological changes of central sensitization in chronic pain patients may result in an amplified response in both intensity and duration of perceived pain [18]. Chronicity of pain may be a surrogate marker for central sensitization in the absence of direct measurement. MacVicar et al. pooled data from three smaller studies and noted a significant, although weak, association of chronicity of pain with outcomes; patients having less than 6 months of pain had better outcomes [2]. The larger study of Kaufmann and colleagues noted a significant association between pain of either less than 3 months or less than 6 months, and better outcomes for both pain relief and functional improvement [3].

The presence of central sensitization, the appropriate delivery of the corticosteroid, and the relative degree of neural compression can affect patient outcomes after TFESI. These factors will not influence the immediate anesthetic block but will be expressed by the 2 weeks post-procedure steroid response; the patient response at 2 weeks is thus much more strongly associated with longer term outcomes that response to the anesthetic blockade.

The study has several weaknesses. It is a retrospective interrogation of a quality assurance database that has a number of patients lost to follow-up. The sensitivity analyses using a variety of imputation strategies did not contradict the findings obtained using only the observed data. The multiple imputation analysis, which is arguably the best imputation strategy employed, yielded an estimated OR very consistent with the observed sample. Therefore, we do not believe that the study's primary findings would have been significantly altered had the data retention rate been higher. There was no stratification by the nature of the compressive lesion; disc herniations, synovial cysts, and fixed stenotic lesions were included. This stratification will be the topic of a subsequent study. The inclusion of all types of compressive lesions in the current study, however, suggests that the results are more broadly applicable to the diversity of lesions observed in clinical practice. Although multiple corticosteroids were used (triamcinolone, betamethasone, and dexamethasone), a prior study on this cohort demonstrated that there was no significant difference in outcomes at 2 months using these agents [8]. The immediate post-procedure NRS assessment by the treating physician rather than an independent assessor may have introduced bias, as patients may seek to please the physician and exaggerate immediate improvement.

Conclusion

Immediate post-TFESI relief of index pain, or appropriate motor blockade, is weakly associated with longer term outcomes of pain relief or functional recovery. The clinical response in pain relief or functional recovery at 2 weeks, when the steroid anti-inflammatory effect is active, is much more strongly associated with corresponding longer term outcomes. Pain physicians should measure patient response in pain relief and functional recovery at 2 weeks post-TFESI as a predictor of longer term success or failure. This may allow more timely clinical decision making regarding subsequent interventions, including repeat injections for incomplete clinical responses, or surgical consultation in non-responders. It will also allow more appropriate counseling of patients regarding expectations of treatment response.

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